

# Notice of Allowability

Application No.

10/507,105

Examiner

Paul C. Martin

Applicant(s)

FUJII, TAKAYUKI

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the pre-appeal brief conference request of 8/10/06.
2. ☒ The allowed claim(s) is/are 11 and 13-15.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>attached hereto</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                                |
|  | 9. <input type="checkbox"/> Other _____   |

## **DETAILED ACTION**

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Ruch on 09/14/06.

#### **IN THE SPECIFICATION:**

At line 1, page 1, please insert: "This Application is a 371 of PCT/JP03/02897 filed 03/12/2003."

#### **IN THE CLAIMS:**

Cancel Claims 12 and 16-25.

Please amend claims 11, 13, 14 and 15 as follows:

11. (currently amended): In a method for measuring an alanine aminotransferase activity in a sample, said method comprising the steps of: bringing the sample into contact with L-alanine, 2-oxoglutaric acid, lactate dehydrogenase, and reduced nicotinamide adenine dinucleotide,

generating pyruvic acid and L-glutamic acid from L-alanine and 2-oxoglutaric acid as substrates by alanine aminotransferase,

~~changing~~ converting pyruvic acid and reduced nicotinamide adenine dinucleotide to lactic acid and oxidized nicotinamide adenine dinucleotide by lactate dehydrogenase, and

measuring a decreased amount of reduced nicotinamide adenine dinucleotide or an increased amount of oxidized nicotinamide adenine dinucleotide,

the improvement comprising bringing the sample into contact with L-alanine, 2-oxoglutaric acid, lactate dehydrogenase, and reduced nicotinamide adenine dinucleotide in the presence of a substance having an activity of inhibiting a lactate dehydrogenase activity, said substance being selected from the group consisting of oxamic acid, oxalic acid, oxalacetic acid, pyruvic acid, phosphoenolpyruvic acid, sodium dodecyl sulfate, lactic acid, and hydroxyglutaric acid, and salts thereof, and the concentration of said substance in the measuring system being a concentration exhibiting the lactate dehydrogenase activity which does not affect the ~~measurement~~ measurement of the alanine aminotransferase activity.

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13. (currently amended): The method according to claim 11 ~~or~~ 12, wherein the substance having an activity of inhibiting a lactate dehydrogenase activity is oxamic acid or a salt thereof.

14. (currently amended): The method according to claim 13, wherein a concentration of oxamic acid or a salt thereof is 0.005 to 5 mmol/L as a final concentration in ~~[[a]]~~ the measuring system.

15. (currently amended): The method for measuring an alanine aminotransferase activity according to claim 11 ~~or~~ 12, wherein a concentration of lactate dehydrogenase is 100 U/L or more as a final concentration in ~~[[a]]~~ the measuring system.

The following is an examiner's statement of reasons for allowance: The closest prior art is Madappally *et al.* (US 4,241,179) which teaches a method for determining a transaminase in a biological fluid and a reagent combination for use in the method. The reference does not teach the reaction mechanism as disclosed by the instant application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Claims 11 and 13-15 are allowed.**

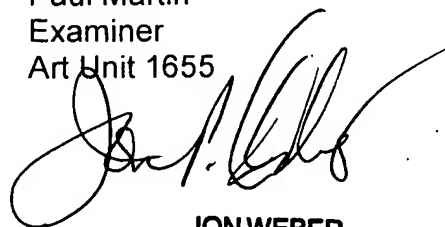
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

09/14/06

Paul Martin  
Examiner  
Art Unit 1655



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**